DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2015

Safe Orthopaedics
Mr. Pierre Dumouchel
Quality Affairs & Regulatory Affairs
Parc des Bellevues – Allée R. Luxembourg – Bat. Californie
95610 Eragny sur Oise
FRANCE

Re: K150092
Trade/Device Name: SteriSpine™ PS Pedicle Screw
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: January 9, 2015
Received: January 16, 2015

Dear Mr. Dumouchel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150092

Device Name

SteriSpine™PS Pedicle Screw

Indications for Use *(Describe)*

The SteriSpine™PS system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion.

SteriSpine™PS System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Special 510k

STERISPINE® PS

SafeOrthopaedics

510(k) SUMMARY

510k	Special 510k
Basis for submission	Addition of a Percutaneous Ancillary Kit to the previously cleared Sterispine™ PS range of products
Submitted by	**Safe Orthopaedics** Parc des Bellevues Allée R. Luxembourg - Le Californie 95610 Eragny sur Oise – FRANCE Phone: +33 (0) 1 34 21 50 00
Contacts	Pierre DUMOUCHEL – Quality affairs & Regulatory affairs Director p.dumouchel@safeorthopaedics.com Regulatory contact : Isabelle DRUBAIX (Idée Consulting) idee-consulting@nordnet.fr
Date Prepared	January 9th 2015
Common Name	Pedicle screw spinal system
Trade Name	Sterispine™ PS Pedicle Screw
Classification Name	Pedicle screw spinal system
Class	III
Product Code	NKB, MNI, MNH, KWP
CFR section	888.3070
Device panel	Orthopedic
Legally marketed predicate devices	Sterispine™ PS Pedicle Screw K112453 manufactured by Safe Orthopaedics (Primary Predicate)
Indications for use	The SteriSpine™PS system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion. SteriSpine™PS System is intended for posterior, non-cervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; tumor; pseudoarthrosis; and failed previous fusion.

Description of the device & Technological Characteristics	The cleared range of SteriSpine™PS system include multiaxial screws and cannulated multiaxial screws with or without extended head (ø5.5, 6.5 and 7.5mm, lengths from 25 to 60 mm) and straight and prebent rods (ø 5.5, 6.5 and 7.5mm, lengths from 30 to 380 mm). Components of SteriSpine™PS system are made of Titanium Ta6V Eli grade conforming to ASTM F136. The SteriSpine™PS range of products is supplied sterile with a sterile single-use set of surgical instruments. The Percutaneous Ancillary Kit added within this submission include (trocar needle, dilators, rod measurer, protection sleeve, funnel body, funnel shaft and funnel impactor). These instruments are supplied as a sterile single-use set to be used with the previously cleared Ancillary Kits.
Discussion of Testing	No testing has been performed for the added components.
Conclusion	The extended range of SteriSpine™PS system is substantially equivalent to its predicate device SteriSpine™PS system (K112453) in terms of intended use, material, design, mechanical properties and function. Verification Activity and Validation Activity demonstrate that components added to SteriSpine™PS system are substantially equivalent to predicates.